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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TAKAHIRO SHIOYAMA, AKANE SUZUKI, and SUNAO TAKEDA

Appeal 2016-001637 Application 13/217,338 Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and RYAN H. FLAX DEMETRA J. MILLS, *Administrative Patent Judges*.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims as directed to non-statutory subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse this rejection.

STATEMENT OF CASE

The following claim is representative.

- 1. A cell analyzer comprising:
- a cytometric device which measures cells that are nuclear stained;
- a display which displays a histogram of a fluorescence intensity by using a result of the measurement by the cytometric device; and

a computer comprising at least one processor configured to obtain a number of strong area cells that are distributed in an area where the fluorescence intensity is stronger than normal cells, and determine a malignancy grade of cancer using the number of strong-area cells and the histogram.

Grounds of Rejection

Claims 1–8 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter.

FINDINGS OF FACT

The Examiner's findings of fact are set forth in the Final Action at pages 2–4.

PRINCIPLES OF LAW

In making our determination, we apply the preponderance of the evidence standard. *See*, *e.g.*, *Ethicon*, *Inc.* v. *Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

In analyzing patent eligibility questions under 35 U.S.C. § 101, the Supreme Court instructs us to "first determine whether the claims at issue are directed to a patent-ineligible concept." *Alice Corp. Pty Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014). If this threshold is met, we move to a second step of the inquiry and "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs.*, *Inc.*, 132 S. Ct. 1289, 1297 (2012); *see also* "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products," (Guidance) issued by the U.S. Patent and Trademark Office, March 2014.

Under step one, the court found that the claims were directed to the abstract idea of "classifying and storing digital images in an organized manner." Id. at 613. Also under step one, the court found that the claims were not directed to a specific improvement in computer functionality, but instead were directed to the "use of conventional or generic technology in a nascent, but well-known environment, without any claim that the invention reflect[ed] an inventive solution to any problem presented by combining the two." Id. at 612. Under step two, the court found that the claims did not recite any limitations that when considered individually and as an ordered combination transformed the abstract idea into a patent-eligible application of that idea. Instead, the recited components and functions were well-understood, routine, conventional activities previously known in the industry. See id. at 613–14. The components were described in "vague, functional" terms that were insufficient to confer eligibility and failed to provide the requisite details to implement the claimed abstract idea. *Id.* at 615.

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Amdocs (Israel) Limited v. Openet Telecom, Inc., 841 F.3d 1288, 1296 (2016).

Lack of Patentable Subject Matter Rejection

The Examiner finds that:

The claimed invention is directed to non-statutory subject matter because the claims as a whole, considering all claim elements both individually and in combination, do not amount to significantly more than an abstract idea. The claims are directed to the abstract idea of determining the malignancy of a sample by analyzing a histogram. The additional elements or combination of elements in the claims other than the abstract idea per se amounts to no more than recitation of generic computer structure that serves to perform generic computer functions that are well-understood, routine, and conventional activities previously known to the pertinent industry. In addition, the instant claims require steps of using a cytometric device. However, the steps of using a cytometric device are data gathering steps, and to not impart meaningful limitations on the abstract idea.

Final Act. 2–3.

Appellants contend that:

The continued rejection is *prima facie* deficient because the rejection does not set forth objective evidence establishing that extracting determining the malignancy of a sample by analyzing a histogram is routine and conventional, namely a building block of human ingenuity. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354-55 (2014) quoting *Mayo* at slip op. 4, 20. Rather, the rejection amounts to a conclusory statement unsupported by any objective evidence or citation that determining the malignancy of a sample by analyzing a histogram is routine and conventional. *See Ex Parte Poisson* (PTAB February 26, 2015), Appeal No. 2012-011084 at 5 ("Instead, the Examiner merely expresses an opinion that 'a set of rules qualifies as an abstract idea.' Yet, absent supporting evidence in the record of which there is none,

the Examiner's opinion is an inadequate finding of fact on which to base the Alice analysis ... The PTO bears the initial burden of establishing a prima facie case of patent-ineligible subject matter under 35 U.S.C. § 101. Because the facts and evidence do not support the finding that claim 1 is 'an attempt to claim a new set of rules for playing a card game' and therefore, necessarily, is an abstract idea, a prima facie case of patent-ineligible subject matter under 35 U.S.C. § 101 has not been established in the first instance by a preponderance of the evidence."").

Reply Br. 4–5.

ANALYSIS

We do not find that the Examiner has provided evidence to support a prima facie case of lack of patentable subject matter. We provide the following additional comment on the Examiner's determinations set forth in the Final Rejection and Answer.

It has been established that "while a claim drawn to a fundamental principle"—i.e., a law of nature, natural phenomenon, or abstract idea—"is unpatentable, 'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Bilski v. Kappos, 130 S.Ct. 3218, 3227 (2010)*. The key issue for patentability, then, at least on the present facts, is whether a claim is drawn to a fundamental principle or an application of a fundamental principle. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1342 (Fed. Cir. 2009); *see also, Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1299 (2012). The Supreme Court has also made clear that the patent eligibility of a claim as a whole should not be based on whether selected limitations constitute patent-eligible subject matter. *See*

Bilski v. Kappos, 130 S. Ct. 3218, 3230 (2010), (citing *Diehr*, 450 U.S. at 185; *Parker v. Flook*, 437 U.S. 584, 594 (1978)).

Claim 1- Step One

Taking up the first step of the patent-eligibility analysis, we find that the Examiner has established that claim 1 is directed to an abstract idea. Looking to the Specification to enlighten us as to the claimed invention, as did the Federal Circuit in *Enfish*, *LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016), we find, as did the Examiner, that the Specification discloses and the claims recite a conventional cell analyzer. *See*, *e.g.*, Spec. 2; Final Act. 6. Additionally, however, the Examiner finds that a cell analyzer with an ability to determine the malignancy grade of cancer does not amount to significantly more than an abstract idea. Final Act. 6.

The present claims are directed to the abstract idea of configuring a conventional processor "to obtain a number of strong area cells that are distributed in an area where the fluorescence intensity is stronger than normal cells, and determine a malignancy grade of cancer using the number of strong-area cells and the histogram. In particular, the Specification, page 16, describes that, "the determination is performed by using the ratio (S/A) of the strong-area cell number S to the total cell number A. The Specification, page 15, describes that

the number S of strong-area cells which are distributed in an area where the fluorescence intensity is stronger than normal cells is obtained (S23). In Fig. 7, the number of cells which are distributed in an area R indicated in the right side of PF [final peak] is obtained. Furthermore, the total cell number A in the histogram of the fluorescence intensity is obtained (S24). In this case, a ratio (S/A) of the strong-area cell number S to the total cell

number A is compared with a threshold TH to obtain the malignancy grade, and the 10 malignancy grade is output on the display device of the computer 7 or by a printer which is not shown (S25).

Appellants argue that there is "something more" (than a mere abstract idea) to their claimed invention, contending:

that the claims amount to significantly more than a mere determination of a malignancy grade of cancer. Specifically, the determination of cancer malignancy is based on "a histogram of a fluorescence intensity" and "a number of strong-area cells that are distributed in an area where the fluorescence intensity is stronger than normal cells."

App. Br. 15.

We are persuaded by Appellants' argument that the Examiner's patent-eligibility rejection is not further supported by sufficient objective evidence that the claimed steps of determining the malignancy grade of a sample by obtaining a number of strong area cells that are distributed in an area where the fluorescence intensity is stronger than normal cells, and determining the malignancy grade using the number of strong-area cells and the histogram, are routine and conventional. App. Br. 10. In other words, the Examiner has not provided evidence that the abstract idea claim steps are routine and conventional.

Based on the balance of the evidence, the patent-eligibility rejection is reversed.

CONCLUSION OF LAW

The lack of patentable subject matter rejection is reversed.

REVERSED